Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Phenobarbital versus Morphine in the management of neonatal abstinence syndrome, a randomized controlled trial

Protocol summary

Summary

Multicentric prospective, randomized, open label, trial on 60 neonates born to illicit drugs addicted mothers and exhibit NAS requiring medical therapy admitted at Vali-Asr and Akbar-Abadi hospitals of Tehran University of Medical Sciences, Tehran, Iran, from April 2009 through February 2014. Inclusion criteria are: 1. neonates born at ≥ 35 weeks of gestation, 2. exposure to addictive drugs in utero 3. demonstration of signs and symptoms of NAS requiring treatment. Exclusion criteria are: 1. neonates born at < 35 weeks of gestation, 2. neonates who had intra uterine growth retardation (IUGR), 3. neonates with congenital anomalies, 4. neonates with major concomitant medical illness requiring oxygen therapy, intravenous fluids or medications, 5. neonates with neurologic abnormality, 6. breastfed neonates, 7. concomitant maternal Benzodiazepine or alcohol use, 8. neonates whose parents refused to give informed consent. After explaining the whole procedure an informed written consent is obtained from the parents, the neonates then will be randomly allocated in 2 groups using the computer random number generator: 1. oral Morphine Sulfate treated group and 2. Phenobarbital treated group. primary outcome of the study is to measure the duration of pharmacologic treatment needed for the resolution of symptoms of NAS. Secondary purposes are duration of hospital stay and requiring adjunctive therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406239568N8**
Registration date: **2014-07-12, 1393/04/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-07-12, 1393/04/21

Registrant information

Name
Golnaz Rezaeizadeh
Name of organization / entity
Maternal Fetal Neonatal Research Center,Tehran University of Medical Sciences, Tehran, Iran
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Recruitment status

Recruitment complete

Funding source

1. Research Deputy of Tehran University of Medical Sciences 2. Maternal, Fetal and Neonatal Research Center, Tehran University of Medical Sciences

Expected recruitment start date

2009-08-15, 1388/05/24

Expected recruitment end date

2014-02-01, 1392/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Phenobarbital versus Morphine in the management of neonatal abstinence syndrome, a randomized controlled trial

Public title

Comparison of Phenobarbital versus Morphine in the

management of neonatal abstinence syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1. neonates born at ≥ 35 weeks of gestation 2. exposure to addictive drugs in utero (determined by maternal history and positive maternal opiate screen during the last trimester of pregnancy) 3. demonstration of signs and symptoms of NAS requiring treatment (3 consecutive Finnegan score of 8 or more or 2 consecutive Finnegan score of 12 or more as calculated every 4 hours by the physician) Exclusion Criteria: 1. neonates born at < 35 weeks of gestation 2. neonates who had intra uterine growth retardation (IUGR) 3. neonates with congenital anomalies 4. neonates with major concomitant medical illness requiring oxygen therapy, intravenous fluids or medications 5. neonates with neurologic abnormality 6. breastfed neonates 7. concomitant maternal Benzodiazepine or alcohol use 8. neonates whose parents refused to give informed consent.

Age

To **5 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Deputy and the Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2009-07-15, 1388/04/24

Ethics committee reference number

88-03-30-9106

Health conditions studied

1

Description of health condition studied

Neonatal Abstinence Syndrome

ICD-10 code

P96.1

ICD-10 code description

Drug withdrawal syndrome in infant of dependent mother

Primary outcomes

1

Description

the duration of pharmacologic treatment needed for the resolution of symptoms of NAS

Timepoint

Every 4 hours the Finnegan Score is measured by the physician till the score falls below 8

Method of measurement

Finnegan Score calculated by the physician every 4 hours

Secondary outcomes

1

Description

The total duration of hospital stay

Timepoint

Measured once at the end of hospital admission

Method of measurement

Measured based on the medical records of the neonate

2

Description

The requirement for adjunctive therapy

Timepoint

Measured daily till the end of neonatal admission

Method of measurement

Measured based on the theraputic and medical records of the neonate

Intervention groups

1

Description

Control Group: In the randomly assigned oral morphine treatment group, initially 1 ml of a 10 mg Morphine Sulfate vial was diluted using 24 ml of distilled water, to make final concentration of 0.4 mg/ml of Morphine, then depending on the Finnegan score drug is administered in 6 divided doses / 24 hours as follow: for a Finnegan score

of 8-10: 0.24 mg/kg/24hours (0.6 ml/kg/24hours), for a Finnegan score of 11-13: 0.48 mg/kg/24hours (1.2 ml/kg/24hours), for a Finnegan score of 14-16: 0.64 mg/kg/24hours (1.6 ml/kg/24hours), and for a Finnegan score of 17 and above: 0.8 mg/kg/24hours (2 ml/kg/24hours) of Morphine Sulfate is administered. These doses of Morphine Sulfate continues until Finnegan score remains below 8 for 72 hours then the drug is weaned gradually by 10% of maximal dose every day until it is entirely discontinued at the cessation dose of 0.1 mg/kg/24hours of Morphine Sulfate.

Category

Treatment - Drugs

2

Description

Intervention Group: In the randomly assigned Phenobarbital treatment group, initially a loading dose of 20 mg/kg IV or IM is administered then if the symptoms persists another 5mg/kg is given every 8-12 hours until the entire loading dose would reach a maximum of 40 mg/kg. The maintenance dose is adjusted based on the loading dose and is initiated 12-24 hours after the last loading dose as follow: for a loading dose of 20 mg/kg the maintenance dose is 5 mg/kg/24 hours, for a loading dose of 30 mg/kg the maintenance dose is 6 mg/kg/24 hours, and for a loading dose of 40 mg/kg the maintenance dose is 8 mg/kg/24 hours administered IM or IV. These doses of Phenobarbital continued until Finnegan score remained below 8 for 72 hours then the drug is weaned gradually by 10% of maximal dose every day until it is entirely discontinued.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-Asr Teaching Hospital, Tehran University of Medical Sciences

Full name of responsible person

Dr. Hosein Dalili

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Akbar-Abadi Teaching Hospital, Tehran University of Medical Sciences

Full name of responsible person

Dr. Kalani

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The Research Deputy of Tehran University of Medical Sciences

Full name of responsible person

Dr. Hosein Dalili

Street address

Vali-Asr Teaching Hospital, Tehran University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

The Research Deputy of Tehran University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Maternal, Fetal and Neonatal Research Center, Tehran University of Medical Sciences

Full name of responsible person

Dr. Mamak Shariat

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Vali-Asr Teaching Hospital, Tehran University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Maternal, Fetal and Neonatal Research Center, Tehran University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Position

Researcher

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty